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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,376	07/01/2003	John S. Patton	0005.15	3703

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NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER
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KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/612,376	<b>Applicant(s)</b> PATTON ET AL.	
	<b>Examiner</b> Gollamudi S. Kishore, Ph.D	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2-15-07
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The response dated 2-15-07 is acknowledged.

Claims included in the prosecution are 26-43.

#### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 31-34 and 39-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-58 of copending Application No. 10/245,705. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 28 in the copending application are drawn to generic pharmaceutical agent in an amorphous dry powder form having the particle sizes of less than 10 microns and claims 32 and 33 identify insulin as one of the pharmaceutical agents. Claim 41 further identifies the composition

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is a spray dried composition; instant claims drawn specifically to insulin and in specific amounts therefore, are anticipated by the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments have been fully considered, but are not persuasive.

Applicant argues that since the present case is in condition for allowance, the present case should be allowed to issue and the double patenting issue should be taken up in the pending application. This argument is not persuasive since according to MPEP 800 (I), if the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn. This application is a later filed application.

3. Claims 31-34 and 39-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-43 of copending Application No. 10/245,706. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to insulin composition in a carrier buffer in a powder form suitable for administration by inhalation. The dependent claim 32 identifies the particle sizes to be less than 10 microns. The dependent claim 28 identifies the buffer to be trehalose, lactose and other sugars. Instant claims are drawn to powdered amorphous insulin compositions with particle sizes below 10 microns and with moisture content of below 10 % containing the same carbohydrate material. The claims in the copending

application thus, are generic with respect to the amounts of insulin and the particle sizes and therefore, instant claims are anticipated by the claims in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained since applicant provides no specific arguments.

4. Claims 31-34 and 39-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent No. 6,358,530. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent are drawn to generic polypeptide active agent and instantly claimed insulin is a polypeptide and therefore, anticipated by the patented claims. In the patented claims, one of the excipients claims is a carbohydrate and the dependent claim 5 identifies the carbohydrate to be lactose, trehalose and others just as in instant claims. The patented claims are generic with respect to the amount of the polypeptide and instant amounts of insulin are therefore, anticipated by the patented claims. The patented claims do not exclude the presence of buffers such as sodium citrate in instant claims.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that that claim 1 in the patent recites 'a dispersibility-enhancing amount of a physiologically-acceptable water-soluble polypeptide and therefore, claims are distinct. This argument is not persuasive since insulin is a polypeptide. Applicant further argues that the claims in the patent do not recite, for example, the insulin composition of claims 31 and 39 or amorphous particles recited in claim 39. These

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arguments are not persuasive since claims 31 and 39 recite insulin amounts whereas the patented claims do not recite any specific amounts and hence could be interpreted as having any desired amount. With regard to applicant's arguments pertaining to the amorphous nature of insulin in claim 39, the examiner points out that the claim 1 in said patent is not drawn to crystalline nature of the polypeptide and therefore, the rejection is still applicable.

5. In view of applicant's arguments, the 103 rejections are withdrawn.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK